



Paul L. Perito
Chairman, President &
Chief Operating Officer

November 15, 2011

Via Federal Express

David L. Ashley, PhD
Director, Office of Science
Center for Tobacco Products
Food & Drug Administration
9200 Executive Boulevard
Rockville, MD 20850

Re: Update to June 6, 2011 Presentation to the Center for Tobacco
Products and July 21, 2011 Presentations to the Tobacco Products
Scientific Advisory Committee

Dear Dr. Ashley:

We are submitting this letter to update certain of the information provided to the Center for Tobacco Products at our June 6, 2011 meeting and in the presentations made to the Tobacco Products Scientific Advisory Committee on July 21, 2011. In those meeting we presented information on our experience with accidental ingestion of our Ariva® and Stonewall Hard Snuff® smokeless tobacco products. We recently became aware of an incident involving the accidental ingestion of one or more Stonewall pieces by a toddler. In order to continue to provide accurate information concerning any such incidents, we are providing the information below relating to this incident.

On Friday, November 4th, we received a telephonic call from the mother of a two-year-old child who stated that her son had apparently ingested one or more Stonewall pieces. At that point the child was nauseated and had vomited at home. The mother was referred to the local Poison Control Center for assistance. Poison Control was able to properly advise and assist because of our collaboration with them regarding our products.¹ The child was taken to the emergency room presenting with hypothermia, dehydration

¹ We advised the National Association of Poison Control Centers shortly after Ariva® began in the marketplace about the product contents and packaging, and asked that this information be shared with local Poison Control Centers throughout the United States. A copy of that letter is attached as Appendix "A".

Executive/Scientific/Regulatory Office

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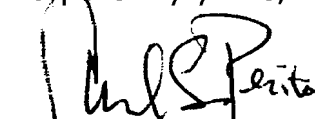
BY: CTP / DCC

and lethargy. Treatment consisted of IV rehydration, pulse oximetry and cardiac monitoring with good response. As a precaution, he was admitted overnight for observation and was released the next day in good condition.

A follow-up call with the child's mother revealed that the child's father had a habit of removing the Stonewall product from our child-resistant blister packs and storing the tabs for a twenty-piece box in a "waterproof, screw top container." The father had left the child unattended in a room where he had access to his father's container. The father later found the child vomiting in the room and the father's container of Stonewall pieces open. The father thought the container was half empty with 6 to 10 lozenges remaining. The exact number of pieces ingested was not known, but was thought to be more than two. No pieces of the product were found in the vomitus at home or in the hospital.

This incident appears to be consistent with other reported instances of ingestion of tobacco and tobacco products that result in nausea and vomiting. We note that in this case, the father of the child removed the Stonewall pieces from our child-resistant blister packs and placed them in a container that was then accessible to the child or perhaps his siblings. As we stated at our presentations, we have always packaged our dissolvable tobacco products in child-resistant blister packs to reduce the risk that a child could obtain access to the product.

Respectfully yours,



Paul L. Perito, Esquire

cc: Curtis Wright IV, MD, MPH
Medical/Clinical Director and
Sr. Vice President of Rock Creek Pharmaceuticals, Inc.
Robert E. Pokusa, Esquire
General Counsel

APPENDIX “A”



October 16, 2002

Ms. Roseann Soloway
Associate Director
American Association of Poison Control Centers
3201 New Mexico Ave., NW, Suite 310
Washington, D.C. 20016

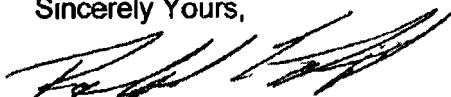
Dear Ms. Soloway:

Our company has developed, and is distributing for sale, a smokeless tobacco product brand-named Ariva™, that is made from tobacco that has been powdered and then compressed into hard pellets, or "cigalett"™ bits. These smokeless tobacco bits are manufactured in child and tamper-resistant blister packaging to prevent toddlers and young children from accidentally ingesting them. Ariva™ is kept in retail stores in the same location as other tobacco products, so that valid proof of age is required for purchase, and it is sold in boxes of twenty cigalett™ bits.

Since this is a new smokeless tobacco product, we want to share with you that each cigalett™ bit contains approximately 1.5 milligrams of nicotine. This is about the same amount of nicotine that an adult would take in after smoking one of what is called a "light" cigarette. We believe that responsible corporate stewardship mandates ensuring that, in the unlikely event that this product is ingested accidentally, poison control centers have the necessary product information immediately available. Please feel free to share this information with the many poison control centers that are located throughout the United States.

If you have any questions, please contact me.

Sincerely Yours,



Robert E. Pokusa, Esquire
General Counsel

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